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1 The effect of dental health education on pregnant women's adherence with toothbrushing and
2 flossing - a randomised control trial.

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Abstract

Objectives: In a three-arm randomized control trial, this study compared the efficacy of dental health education (DHE) with or without a planning intervention on adherence to oral health related behaviours.

Methods: Women (N=154) in their second trimester of pregnancy attending three maternal healthcare clinics in Kuwait completed an assessment of social cognitions and oral health behaviours before a debris and gingival assessment (Plaque Index (PI), Gingival Index (GI) was undertaken; this was repeated at one month. In addition to treatment as usual (TAU), which was a demonstration of OH practices, intervention participants received one of two interventions: (1)DHE, which targeted social cognitions; or (2)DHE and Planning (DHE&P), which targeted social cognitions and intentions to undertake oral health behaviours. The TAU group was given a standard oral hygiene leaflet.

Results: At **Time one (T1)** 154 women were eligible and randomly allocated to the three groups respectively: Treatment as Usual (TAU) =53; DHE=53; DHE and Planning=48. At **Time two (T2)** the number of women in each group completing the intervention (N=90) was respectively: TAU=28; DHE=30; DHE&P=32. There were no demographic differences between the groups at baseline. The mean age of women was $27.80 \pm SD 5.40$, 43% (n=38) had a high school level education. A mixed factor ANOVA analysis demonstrated that all women improved their PI ($F=94.343$ $df=1$ $p=0.001$) and GI ($F=73.138$ $df=1$ $p=0.001$) scores. There were no differences in self-reported oral hygiene and PI and GI by intervention group. The **social cognition models (SCM)** constructs changed over time in all women (N=90) except barriers to attendance ($F=1.067$ $df=1$ $p=0.305$). There were no statistically **significant** differences in SCM constructs by intervention group at T2. All women reported increasing the frequency of tooth brushing and flossing.

Conclusions: The provision of information using a simple leaflet improved the adherence of Kuwaiti pregnant with toothbrushing and flossing advice, while the addition of DHE targeting social cognitions and planning conferred no additional benefits.

Introduction

Pregnancy is thought to be an important and critical period for imparting oral health information and supporting women to adopt positive oral health behaviours¹. Studies have emphasised the importance of good oral hygiene procedures to prevent maternal gingivitis²⁻⁴. The main goal of dental health educators for pregnant women is to establish and maintain positive oral health behaviours during pregnancy. A qualitative study with Kuwaiti pregnant women⁵ showed that they had inaccurate dental health knowledge and held unhelpful attitudes and beliefs in relation to oral health behaviours. Few women in the study were aware of gingivitis or periodontal diseases, and many reported that they stopped cleaning their teeth during the first trimester because of bleeding gums, pregnancy sickness or both. There was a clear need to address knowledge gaps and to establish positive oral health behaviours.

Although knowledge is necessary for behaviour change, it is not sufficient for the adoption of new health behaviours⁶. Within the dental setting, there is evidence that social cognition models (SCMs) have merit in enabling behaviour change⁷, although there is also the view that 'one size fits all' approaches are inappropriate⁸; in particular, it has been suggested that individual behaviours may need to be tackled by different approaches, and the latter will depend on the complexity of those behaviours. Indeed, established SCMs -such as the Theory of Planned Behaviour (TPB) and the Stages of Change model-have been severely criticised generally^{9, 10} but also specifically in terms of their relevance to oral health behaviours^{11, 12}.

Given the above critique, this study focused on social cognitions that an earlier qualitative study⁵ had shown were important in shaping the target group's oral health behaviours. These were knowledge, attitudes, subjective norms and barriers to oral health behaviours. In addition, we sought to explore the efficacy of implementation intentions. These are intentions that encourage the individual to plan and specify exactly when, where, and how they will engage in a specific behaviour (that is, "I intend to do x whenever the situational conditions y are met")¹³. Previous dental studies have shown that use of implementation intentions increases the likelihood of adherence to good oral hygiene behaviour^{14, 15}. Additionally, developing action plans has been shown to encourage regular tooth brushing behaviour^{16, 17} and flossing behaviour¹⁸.

The aim of the this study was to examine whether dental health education (DHE) with or without a planning intervention increased the frequency of pregnant women's oral hygiene. Two interventions were tested: (1) DHE which targeted social cognitions to include knowledge; and (2) DHE and Planning (DHE&P) which, in addition to DHE, targeted implementation intentions. We hypothesised that positive change in social cognitions would increase the frequency of toothbrushing and flossing. It was further hypothesised that different levels of the intervention (TAU, DHE, DHE&P) would affect social cognitions in the three groups.

Methods

The design was a single-blind randomised control trial that enrolled participants from three governmental outpatient maternity clinics in Kuwait. Women at each clinic were randomly allocated (with an allocation ratio 1:1:1) to one of three groups: treatment as usual (TAU); dental health education (DHE); or DHE and planning (DHE&P). This study had a 4-week repeated measurement design (Table 1). Four weeks was chosen on the basis of previous work using the same time frame^{15, 19-21} but also as a practical period coinciding with the women's attendance at the maternity clinic.

Participants were recruited between February (08/02/2011) and August (30/08 /2011). All Kuwaiti pregnant women who were in the second trimester of pregnancy (4 to 7 months) and attended the selected governmental maternal healthcare clinics were eligible and invited to participate in this study. Women were excluded if they were unable to provide informed consent, had pregnancy complications, were edentulous, smoked or used tobacco products, or were not Kuwaiti nationals. At Time 1 (baseline), eligible expectant mothers were approached by a dental hygienist (DH) to take part in the study. After informed written consent was obtained, they were asked to complete a self-administered questionnaire. The DH then assessed the women's plaque index (PI)²¹ and gingival index (GI)²². The researcher (SAK) then met each woman and randomly allocated her to a group, based on a random allocation number sequence devised by a statistician. The researcher then delivered the allocated TAU or interventions in a private office and provided a dental pack that included a toothbrush, a family-strength fluoridated toothpaste and a packet of dental floss. The researcher delivered all three intervention arms. Four weeks later, at T2, participants returned and completed the original T1 questionnaire again. GI and PI scores were re-assessed by the DH who was masked to the participants' group allocation. At the end of the trial, women in

the TAU group were offered the DHE intervention. The study was approved by both the local Kuwait Ethical Committee and the King's College London research ethics committee (BDM/10/11-32).

The TAU group received a standard dental hygiene information leaflet available in the waiting room of dental clinics in Kuwait. The leaflet included information on tooth brushing and dental flossing. To ensure consistency, the researcher provided a brief, standardised scripted explanation of the information covered in the leaflet with the participants, and demonstrated brushing and flossing techniques on a plastic model of the mouth, as would occur in routine dental practice in Kuwait.

The DHE intervention group was also provided at T1 with the oral hygiene information leaflet and discussion as per the TAU group. In addition, the DHE group participants received a dental health education (DHE) booklet specifically designed to be culturally appropriate for pregnant women which was informed by the previous qualitative study⁵. The booklet targeted social cognitions, including (primarily) knowledge and (secondly) the social cognition constructs (attitudes, subjective norms, barriers, intention) identified from the previous qualitative study⁵. The booklet provided information concerning basic dental health information that women might require in general and during pregnancy. It gave specific advice about the importance of oral hygiene during pregnancy, along with information on gum and dental health during pregnancy, dental visiting and seeking dental care during pregnancy, and when to brush after morning sickness (vomiting). Participants were asked to read the booklet before leaving the research intervention venue and were encouraged to ask any questions about the information in the booklet.

At T1, the DHE and planning (DHE&P) intervention group received the DHE intervention, but they were also asked to write a plan of when, where and how they would brush and floss their teeth, what obstacles would stop them from doing so, and how they would overcome these obstacles^{10, 17}. The three groups were provided with the same amount of interaction time demonstrating the tooth brushing and dental flossing methods. Four weeks later, women in all three groups returned for follow-up.

The primary outcome was adherence to good oral health behaviour using objective measures (PI²¹ and GI²²) and self-report of tooth brushing and flossing frequency in the last seven days. Since adherence to tooth brushing and dental flossing instructions could not be observed directly, proxy measures were used. This approach is well established in

160 interventional studies of this type¹². The PI assesses the effectiveness of plaque control in the
161 previous 24 hours, whereas the GI was used as an objective measure of participants'
162 adherence to effective brushing and flossing over the period of the intervention (PI and GI
163 were assessed at baseline and four weeks post-intervention^{23, 24}). The DH was trained and
164 calibrated to assess PI and GI by an experienced periodontist. The inter-examiner agreement
165 between the gold standard periodontist and the DH was 95% for PI and 91% for GI. It was
166 not feasible to determine intra-examiner variability during the study, because most
167 participants left the clinic once their examinations were complete and were unwilling to stay
168 after their scheduled appointment. The PI and GI measurement process was modified to
169 exclude probing, in order to comply with ethical requirements in Kuwait which precluded the
170 researcher from performing any invasive procedure such as probing or staining of the teeth on
171 pregnant women. Instead, observations using good light and a disposable dental mirror were
172 used in the pre-and-post intervention assessments.

173 A questionnaire was used to assess the secondary outcomes of social cognitions
174 (knowledge, attitudes, subjective norms and barriers to oral health behaviours) and self-
175 reported tooth brushing and flossing. Most of the items included in the questionnaire were
176 previously validated²⁵ or derived from similar research^{6, 18, 26-30}. In addition, there were seven
177 additional items arising from the qualitative study⁵. Face validity of the measure was
178 established by a panel of behavioural science and dental practitioner experts prior to inclusion
179 in the study.

180 The correct responses for items relating to the knowledge construct were scored 1 and
181 incorrect answers scored 0. In order to ensure that reverse scoring did not affect the measure,
182 the positive responses to attitudes, subjective norms and barriers were scored from 5 to 1 and
183 negative responses were scored from 1 to 5. This meant that a high score always meant a
184 positive attitude, positive subjective norms and reduced barriers.

185 Pilot work on the questionnaire with 12 women selected from the population of
186 interest in the maternal child clinics informed the main measure. The questionnaire typically
187 took between 20 to 30 minutes to complete.

188 The study was estimated to have 80% power at the 5% significance level to detect
189 changes of 25% vs. 50% in the proportions of pregnant women assessed to have improved
190 GI, for which 66 women per group were required. This sample size also provided 80% power
191 to detect effect sizes of 0.5 and above between the groups in terms of the clinical outcomes of

the PI and GI. Assuming a 20% attrition rate, the planned sample size was a total of 246 mothers, with 82 enrolled in each group.

Randomisation and blinding

The DH enrolled the participant and gave her a number based on the sequence of their participation. She then asked participants to complete the questionnaire and made clinical assessments. The DH sent the woman with her number to the researcher, who was in a separate private room. The researcher checked the sequence number against the allocation sequence and delivered the TAU or intervention as stipulated in the allocation sequence tables. The participant was thanked and a date agreed for the T2 follow-up. Only the researcher had access to the allocation sequence. At T2, the DH refrained from discussing the contents of the women's visit with the researcher at T1. She then asked participants to complete the questionnaire, after which she made the clinical assessments.

The DH who recorded the PI and GI and administered questionnaires at T1 and T2 was blind to group allocation. The researcher who delivered TAU and the interventions was aware of the group allocation, but was not involved in recording or assessing outcomes. The location and interaction time spent with each participant was similar across the three groups and it is likely that they were unaware that they had received different educational content. However, if the women had discussed the resources they received with other women in the study, they would probably have become aware that the education content in each arm was different. Data were analysed before group allocation was revealed.

Statistical methods

Per protocol analysis of data was undertaken. The demographic and health characteristics of participants in each group were described using descriptive statistics. A mixed analysis of variance (ANOVA) was undertaken (with repeated measures on time, between measures on type of intervention) to compare the means between the three groups on primary (PI, GI) and secondary outcomes (knowledge, attitudes, subjective norms, and barriers to oral health behaviours) and self-report of tooth brushing and dental flossing activity. Missing items were replaced with the mean scores for that variable³¹. The reliability analysis score for the questionnaire across all 60 items was Cronbach alpha=0.843.

Results

Figure 1 shows a CONSORT flow chart for this RCT. It proved unfeasible to recruit the target sample of 246 in the seven-month time frame for the study. Of the 232 women screened, 171 were randomly allocated to groups. Twenty-nine of those women refused to take part and 32 were excluded because they did not meet the inclusion criteria. Of the 171 randomised, 17 did not complete Time 1 measures either because they were not interested or said they did not have time to complete the questionnaire.

Of the remaining 154 women randomised, 90 (58%) completed the study, with 28/53 (53%) completing measurements in the TAU group and 30/53 (57%) and 32/48 (67%) completing in the DHE and DHE&P group respectively.

Table 2 summarised the characteristics of women by allocated group at baseline. There were no differences amongst the groups at baseline with the exception of educational status, where there was a statistically significant differences in the DHE group, women in DHE group were more likely to have completed education to a graduate level compared to women in the TAU and DHE&P groups who were more likely to have fewer formal qualifications ($P=0.021$). Women in all three groups at T1 had similar PI and GI scores and self-reported similar frequencies in tooth brushing and dental flossing behaviours respectively over the previous seven days. Only 38% reported tooth-brushing twice daily and 61% never used floss, attitudes to oral health were unfavourable. There were no differences in social cognitions between the three groups: knowledge, attitudes, subjective norms, brushing barriers, flossing barriers, attendance barriers, attendance barriers and snack barriers. Knowledge levels were low, with mean scores showing that women failed to get at least 50% of questions right at baseline.

Outcomes and estimation

The primary outcomes of PI and GI improved across all groups by 42% [$F(1, 87) = 94.34, P=0.0001$] and 30% [$F(1, 87) = 73.14, P=0.0001$] respectively, suggesting more effective and sustained plaque control over a brief period of 4 weeks. However, there was no benefit attributable to the type of intervention received (Table 3).

Similarly, all women self-reported more frequent tooth brushing and flossing at T2, but there were no differences in self-reported frequency between intervention groups and TAU (Table 4).

For the secondary outcomes (social cognitions in relation to knowledge, attitude, social norms and barriers), all women regardless of the intervention they received or TAU were more knowledgeable about oral health [$F(1, 87) = 295.63, P = 0.0001$], had more positive attitudes [$F(1, 87) = 47.107, P = 0.0001$] and more positive social norms [$F(1, 87) = 9.297, P = 0.003$] and perceived fewer barriers to undertaking oral health behaviours (brushing [$F(1, 87) = 13.254, P = 0.0001$], flossing [$F(1, 85) = 31.724, P = 0.0001$] and snacking [$F(1, 85) = 9.900, P = 0.002$]) at T2 (Table 3). The exception to this was the perception of barriers to dental attendance [$F(1, 87) = 0.001, P = 0.981$] which did not change from T1 to T2. The changes in social cognitions occurred regardless of group allocation.

There were improvements across all three groups in knowledge, attitude, and subjective norms in relation to oral health and a reduction in tooth brushing barriers, dental flossing barriers and snacking barriers. Perceived barriers to dental attendance did not change.

Discussion

This randomised control trial found that pregnant Kuwaiti women who initially had very low levels of knowledge, poor attitudes, and unfavourable subjective norms in respect of oral health were found to have improved PI and GI- periodontal health four weeks post-intervention. The clinical improvement was supplemented by improvements seen in self-reported tooth-brushing and flossing over the same period. Nevertheless, there was no benefit attributable to the type of intervention received over and above TAU.

For the secondary outcomes (social cognitions in relation to knowledge, attitude, social norms and barriers) women with poor scores on all of these measured constructs were found to show improvements four weeks later; thus, they were more knowledgeable about oral health, had more positive attitudes and more positive social norms and perceived fewer barriers to undertaking oral health behaviours regardless of the intervention they received. Barriers to dental attendance were the only domain that did not change from T1 to T2.

In this study, providing basic oral hygiene information with a brief discussion and demonstration of oral hygiene skills, as occurred in the TAU group, was sufficient to support improvement in dental health behaviours for participants who had very low levels of oral health knowledge at baseline. This confirms the assertion of Conner and Norman, who suggested that knowledge is necessary but often not sufficient for behaviour change⁶. These

data also show that addressing capability (by the provision of knowledge to a group of people having literally non-existent knowledge resources) was enough to initiate behaviour change in a sample of pregnant women³². We propose that, with samples which lack the very basic building elements of behaviour change (that is, knowledge), providing such knowledge in a relevant setting may well be a sufficient intervention. Theoretically, these findings suggest that, for more complex behavioural interventions (such as those building on planning and action monitoring), participants need to be at a sufficiently proficient level with the behaviour in question for these interventions to be able to yield improvements over and above those that a simple intervention might provide. Furthermore, it is possible that a ceiling effect occurred in the present study with the impact of giving information providing the maximum possible benefit for behaviour, such that an additional intervention had no room to further improve the behaviour.

The attrition rate in this study, while in line with other similar studies³³, was high overall (42%) with completion rates in the TAU group lowest at (53%) and the DHE&P group highest at 67%. However, there were no significant differences in demographic characteristics, objective and self-report of oral hygiene behaviours and social cognitions between women who completed the study and those who did not. Some of the reasons for non-completion might be related to the characteristics of the intervention (women may not have liked the booklet or were too busy to put time aside at their maternity visit to discuss oral health) or to the processes used to measure the outcomes (they may have found the questionnaire too long or the plaque and gingival scoring too invasive) or to study timing (part of the study took place during a fasting-focused religious festival). Future studies should investigate women's views of the interventions *post hoc* and include an objective assessment of the acceptability of the interventions.

It is interesting to note that women in the DHE&P group had the highest completion rate (67%). Perhaps the DHE&P group's completion rates are related to greater engagement associated with the development of individual plans which enabled women to form the intentions to undertake behaviours. Notwithstanding the issues with intentions not predicting actual behaviours¹⁰, future studies should validly measure intention to engage in health behaviours through objective and subjective measures of adherence. Furthermore, the use of visual cues to encourage self-monitoring of performance such as plaque disclosing tablets and liquids may benefit some participants.

The intervention was delivered by female dental hygienist who would not have been familiar to the women taking part in the study. It is possible that using local dental healthcare professionals familiar to the participants may have led to greater engagement with the intervention and even larger improvements in periodontal health. There is some evidence that the use of local healthcare professionals to deliver motivational interventions is effective³⁴.

Another important limitation was the requirement by the ethics committee in Kuwait to modify our objective measure of oral hygiene (PI and GI). While the clinical scores assessed improved from Time 1 to Time 2 regardless of the type of intervention, the PI and GI were not applied according to the standard method for using these indices^{22,23}. This may have affected the validity of the PI and GI in this study, although, at T1 and T2 the PI and GI were assessed in the same way. Thus, the only real effect of this shortcoming is to limit the comparability of the data with those from other studies.

This study is one of only a few which have been conducted with pregnant women in a Middle Eastern country³⁵⁻³⁷ where there are different levels of knowledge and social norms about dental care during pregnancy. Previous studies addressing the oral health information needs of pregnant women have been undertaken in Europe, US and Australia, reflecting cultural and social norms there^{1,38,39}. Our findings are, of course, specific to the local, non-Western cultural setting and to women at an early stage of pregnancy and may only apply to such settings. While the development of SCM occurred in the West, there is little work which suggests that these models apply in a Middle Eastern country with different social norms and culture. Indeed, a recent critique of these models in dental settings suggests that they are flawed. It calls for a new paradigm in approaches to behaviour change which rejects slavish reliance on models and proposes approaches which are relevant and match the complexity of the behaviour change needed¹¹.

In conclusion, in Kuwaiti pregnant women with poor basic knowledge about oral health, there was improvement in objective and self-reported measures of oral hygiene and in knowledge and other social cognitions regardless of the complexity of the behavioural intervention provided. The addition of Dental Health Education (with or without a planning intervention) conferred no additional benefit in terms of improving the adherence of pregnant women to positive oral hygiene behaviours.

Other information

This RCT was not registered, but a full study protocol was prepared and is available from the author. This study was undertaken as part of a PhD study funded by the Kuwait government

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